

Remarks:

Reconsideration of the application is requested. Claims 1-6, 8-24 and 49-73 are now in the application. Claims 1, 4, 6, 8, 23, 49, 51, 52 and 57 have been amended. Claims 9-17 were previously withdrawn. Claims 58-73 have been added.

Interview Summary

Applicant appreciates the courtesies extended to Applicant's representatives (Paul Bianco and Michael Fluhler) and Applicant (Peter Bonutti) during a telephonic interview with Examiner Szpira on November 12, 2009. The amendments and remarks presented herein reflect those discussed during the interview, and Applicant respectfully submits that this Response satisfies the requirements of MPEP §713.04. More particularly, independent claims 1 and 71 recite the claim language suggested in the Examiner's Interview Summary (object extending through the fastener substantially unobstructed).

35 USC § 112

In item 2 of the Office action, the Examiner rejected claim 49 because the term "the suture" lacked antecedent basis. Claim 49 has been amended. The term "the suture" has been corrected to --the object--. This term has antecedent basis in claim 1 of the instant application. Accordingly, amended claim 49 is now definite.

35 USC § 102—Merritt '950

In item 5 of the Office action, the Examiner rejected claims 1-8, 19, 24, and 50-53 as being anticipated by Merritt (US Pat. No. 5,208,950) under 35 USC § 102(b). The rejection has been noted and, as set forth in more detail below, Applicant respectfully submits that the claims presented are not taught or suggested by Merritt.

Before discussing the prior art in detail, a brief review of the invention as recited in claim 1 is provided. Amended claim 1 calls for an implantable fastener that includes the following features:

a first section including a first surface and further including an extension member extending from said first surface, and

a second section including a second surface, said second surface opposing said first surface and being configured for receiving the extension member, the first and second sections being bondable together with the application of an energy source;

said first surface being configured to abut the object and said second surface being configured to abut the object; and

wherein the object extends through the fastener substantially unobstructed.
(Emphasis added by Applicant.)

Merritt '950 teaches an elastic cord lock such as one used in a vehicle restraining net. Merritt '950, col. 4, lines 35-36, teaches that cord lock is preferably snapped together and that it could be connected with adhesive or ultrasonic welding. The assembled cord lock does not compress, it has fixed dimensions.

Because Merritt '950 does not teach an implantable fastener, the invention according to claim 1 is not anticipated. Further, and as discussed during the interview, Merritt requires that the elastic cord go through a tortuous path through the lock. The tortuous path is required in order to ensure that the elastic cord does not slip with respect to the lock. With the implantable fastener as set forth in claim 1, the object extends through the fastener substantially unobstructed.

Another feature of the invention not taught by the prior art is detail as to what parts are being bonded to each other. Merritt '950 provides no teaching as to what is being ultrasonically welded. Merritt '950 does not teach which piece is to be ultrasonically welded to what other piece. Merritt '950 merely states that ultrasonic welding could be used to connect the two parts instead of snapping or adhesive.

The invention according to claim 64 specifies that the center extension member (254) as shown in Figs. 30A and B (for example) is being welded to the second surface.

Another difference between the invention according to claims 59 and 60 is that a first surface (754) compresses relative to a second surface (756) when the fastener is being welded. *See* paragraphs [0369] through [0372] of the published application. The mechanism for the holding force is in part the compression between the first surface and the second surface and also the formation of a form locking shape around the object.

In Merritt '950, the halves of the cord lock never move closer together. The mechanism for holding the elastic cord is the tortured path through the cord lock-- not the sandwiching of the cord.

The invention according to claim 61 is novel compared to Merritt for the additional reason that Merritt '950 teaches a cord lock for use in a vehicle. The invention according to claim 61 is an implant for use within a patient's body. The material of the implant is a biocompatible material. In contrast, Merritt '950 is silent as to the material because it was never contemplated to place the implant into a patient.

The invention according to claim 63 is compatible for the additional reason that Merritt '950 does not teach a cord lock that holds a rigid object. Support for a rigid object can be found, for example, in paragraph [0080] of the published application. Merritt '940 works by stretching an elastic cord through a tortured path.

The invention according to claims 66-67 specifies how the energy is to be applied to the fastener. Merritt '950 provides no teaching or suggestion of how to apply the energy for the ultrasonic welding described in the specification.

With respect to claim 4, while the sketch provided by the Examiner in the outstanding office action could be considered as showing parallel paths, those paths are not the paths that hold the elastic cord. The elastic cords follow a tortured path around cylindrically-shaped projections

(80); *see* col. 4, line 8. Because Merritt '950 does not show all of the features of claim 4 as amended, claim 4 is novel.

35 USC § 102(b)—Egan '324

In item 6 of the Office action, the Examiner rejected claims 1, 18, 49, and 54 as being anticipated by Egan (US Pat. No. 5,174,324) under 35 USC §102(b).

In the Office action, Egan '324 is mischaracterized. The Office action asserts that “[T]he first and second section being bondable together with the application of an energy source (ultrasonic energy; column 5, lines 23-37).”

In fact, Egan '324, col. 5, lines 18-22, states “Alternatively, if the suture retaining device is made of a material similar to that of the suture strands, application of energy to the suture retaining device can cause it [i.e. the suture retaining device] to melt with the suture strands, thereby effecting a bond between the suture strands and the retaining device.” (Emphasis added by Applicant.) The bond is between the strands and the retaining device. The bond is not between the parts of the retaining device.

Claim 1 of the instant application recites, “The first and second sections being bondable together with the application of an energy source.”

At least because this feature is not taught by Egan '324, claim 1 is novel. Claims 18, 49, and 54, which all ultimately depend on claim 1 are also novel at least based on their dependency.

New claims 58-60 are novel over Egan '324 at least because Egan '324 does not teach compressing the fastener, particularly, the extension member when energy is being applied.

Claim 63 is novel over Egan '324 because Egan '324 only teaches a suture. Egan '324 does not teach a rigid object being held.

Claims 64-67 are novel with regard to Egan '324 because Egan '324 does not describe any details regarding how the parts are being ultrasonically welded.

35 USC § 103—Egan ‘324 in view of Hart ‘824

In item 9 of the Office action, the Examiner rejected claim 20 as being unpatentable under 35 USC §103(a) over Egan ‘324 in view of Hart (US Pat. No. 5,630,824).

Claim 20 depends upon claim 1. For the reasons discussed with regard to the anticipation rejection involving Egan, Egan in light of Hart ‘824 fails to form a *prima facie* case of obviousness. Accordingly, claim 20 is patentable over the art.

35 USC § 103--Merritt ‘950 in view of Tokushige et al. ‘634

In item 10 of the Office action, the Examiner rejected claim 21 as being unpatentable under 35 USC § 103(a) over Merritt ‘950 in view of Tokushige et al. (US Pat. No. 5,866,634).

Tokushige et al. teaches a biodegradable shrink film that shrinks at a lower temperature. Accordingly, Tokushige et al. does nothing to remedy the deficiencies of Merritt ‘950.

Further, one with ordinary skill in the art would not combine Merritt ‘950 with Tokushige et al. ‘634 because lowering the shrink temperature (as taught by Tokushige et al.) is not applicable in cases where the fastener is being heated with an energy source to cause bonding.

Accordingly, the invention described in claim 21 is not obvious and is patentable over the prior art.

35 USC § 103—Egan ‘324 in view of Bartlett ‘372

In item 11 of the Office action, the Examiner rejected claims 22 and 23 as being unpatentable under 35 USC § 103 over Egan ‘324 in view of Bartlett ‘372.

Claim 22 of the instant application recites that the fastener includes viable cells.

Bartlett ‘372 teaches allograft bone tissue grafts. There is nothing in Bartlett ‘372 that teaches that the allograft tissue contains viable cells.

Therefore, Egan '324 in view of Bartlett '372 fails to teach or suggest all of the features of claim 22. Accordingly, the references fail to form a *prima facie* case of obviousness. Claim 22 is therefore patentable.

Claim 23 is patentable because Egan '324 in view of Bartlett '372 fail to form a *prima facie* case of obviousness as is required under 35 USC § 103(a). Claim 23 recites a fastener that includes pharmaceutical agents, with at least one of the pharmaceutical agent being osteoinductive. The prior art does not teach or suggest an implant that includes pharmaceutical agents as set forth in claim 23.

The Examiner cited Bartlett '372 as teaching a pharmaceutical agent—hydroxyapatite. Even if hydroxyapatite is considered a pharmaceutical agent, hydroxyapatite is osteoconductive, but not osteoinductive. Because hydroxyapatite does not induce bone growth but is merely a support for growth, hydroxyapatite does not qualify as a pharmaceutical agent as recited in claim 23.

Because the prior art fails to teach and suggest all of the features of claim 23, the invention according to claim 23 is patentable and not obvious.

35 USC § 103—Egan:

In item 12 of the Office action, the Examiner rejected claims 55-57 as being unpatentable over Egan '324 under 35 USC § 103(a).

The invention according to claims 55-57 and new claim 69 are not obvious over Egan '324 because the invention taught by Egan '324 would not work with materials others than the specific suture material mentioned in the specification.

Egan '324 teaches ultrasonically bonding sutures made of specific materials to surfaces of a fastener and of bonding strands of the suture to itself. The melting of the suture strands is the key; *see* col. 5, lines 13-23. Furthermore, Egan '324 teaches away from melting the fastener itself; *see* col. 1, lines 17-38.

So, one with ordinary skill in the art reading Egan '324 would only be suggested to use an object that is bondable. The specific materials of the suture in Egan '324 give the overall bonding qualities to the fastener.

Tissue and metal are not bondable (at least by the means that are practical and suggested by Egan '324). So, one with ordinary skill in the art reading Egan would not be suggested to replace the suture made of bondable material with non-bondable material such as tissue and metal.

Therefore, Egan '324 does not teach or suggest all of the features of the invention according to claims 55-57 and 69. The invention according to those claims is not obvious and patentable.

With regard to the Examiner's argument regarding intended use, Applicant believes that the difference in claims 55-57 is more than intended use. That is, the fastener (and not just the object) must be bondable in the invention according to claims 55-57. This feature is not suggested by Egan. Furthermore, the material of the object is positively claimed in claim 69.

Other arguments:

Claim 68 is novel because in Egan '324, col. 4, line 66, through col. 5, line 6, Egan teaches that the fastener should be rounded and sharp discontinuities should be avoided. In contrast, the fin shaped extension member in the invention provides a sharp discontinuities.

Applicant has added new independent claim 71 and dependent claims 72 and 73 and respectfully submits these claims are patentable over the art of the record. Claim 71 is directed to an implantable fastener for securing an object relative to body tissue. The fastener has a first section including a first surface and an extension member extending from the first surface; and a second section including a second surface, the second surface opposing the first surface and configured for receiving the extension member. The first and second sections are bondable together with the application of an energy source to secure the object to the fastener. The first surface and the second surface move closer to each other with the application of the energy source to thereby secure the object to the fastener, with the object extending through the retainer substantially unobstructed. For reasons discussed with respect to the pending claims, Applicant

respectfully submits that the cited art does not teach or suggest all of the features of claim 71, as well as its dependent claims.

Conclusions:

The claimed invention involves a medical device fastener that has two parts that are bonded to each other while being compressed to hold an object between the parts. In contrast, the prior art (i.e. Merritt '950) teaches a cord lock with two parts that are held together with ultrasonic welds; the parts do not compress to hold the object therebetween. Egan '324 shows a fastener where the object forms a bond to the fastener but the fastener parts are not bonded to each other. Accordingly, one reading with ordinary skill in the art would have no suggestion of how to make the claimed invention.

In view of the foregoing, reconsideration and allowance of claims 1-6, 8-24, and 49-73 are solicited. In the event the Examiner should still find any of the claims to be unpatentable, please telephone counsel so that patentable language can be substituted.

Petition for a two month extension is herewith made. The extension fee for response within a period of two months pursuant to Section 1.136(a) in accordance with Section 1.17 is enclosed herewith.

If any further extension of time for this paper is required, petition for extension is herewith made.

Appl. No. 10/780,444
Amendment Dated December 4, 2009
Reply to Office Action of July 7, 2009

No additional fee is believed due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 782-A03-023).

Respectfully submitted,

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